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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LARIVIERE, GRUBMAN & PAYNE, LLP
1 LOWER RAGSDALE, BLDG. 1, SUITE 130
P.O. BOX 3140
MONTEREY, CA 93942

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,362

Applicant(s)

LAN ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2003 as Paper Number 4.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 27-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 27-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

1. Applicants' response and amendment filed January 31, 2003 as Paper Number 4 to election requirement in Office Action mailed January 08, 2003 as paper Number 3 is acknowledged and entered.
2. Claims 1-22 and 24-26 have been cancelled.
3. Claims 23 and 27 are amended.
4. Claims 23 and 27-49 are pending.

Restriction/Election

5. Applicants' election with traverse of Group II, Claims 23 and 27-49 filed January 31, 2003 as Paper Number 4 is acknowledged. Because applicant did not distinctly and specifically present the reasons for traversal, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the restriction requirement is deemed proper and is made FINAL.
6. Claims 23 and 27-49 are examined on merits.

Objection to Information Disclosure Statement

7. The information disclosure statement filed March 21, 2003 as paper number 5 is deficient. It has been entered, but only Reference 1 has been considered because references 2 and 3 are neither in English, nor there is an English abstract for those references.

Objection To Specification

8. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., Page 6, Paragraph 0022 "To use the solid culture method described above, one can get the solid Zang Zhi". The solid Zang Zhi can be produced by any of the processing methods to those skilled in the art, for example water or alcohol can be used to extract the active constituents". The examiner suggests that the applicants should carefully revise the specification including the abstract to make the specification clearly comprehensible. The applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). For example, correction of

the following is required: Page 5, lines 18-19 because there is no reference to sawdust medium in the previous paragraph 0019 (i.e., Page 5, Lines 12-16).

Objection To Abstract

10. The abstract of disclosure for this application recites abbreviation (e.g., PP) that should be fully written for an artisan of the art to understand the invention.

Claims Objection

11. Claims 23 and 27 are objected to because of the recitation, "cultural". The art-recognized term is "culture". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

12. The following is a quotation of 35 U.S.C. § 101 that form the basis for the rejections under this section made in this Office action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 23 is rejected under 35 U.S.C. § 101 as being drawn to nonstatutory subject matter. As written, the claim is drawn to a biological material *per se*, which is a product of nature. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C. §101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Inoculant Co. 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980). The Examiner suggests that applicant use the language "an isolated, or cultured fruiting body" in connection with the microorganism to identify a product that is not found in nature.

Claim Rejections Under 35 U.S.C. § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 23 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For example, Claims cited *supra* recite "same characteristics of physiological activities of triterpenoid as that of wild Zang Zhi". However, the specification does not teach the characteristics of wild Zang Zhi or triterpenoid obtained from said Zang Zhi.

16. Claims 32-33, 38-39, 43-44 and 47 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a composition and a method to inhibit liver disease and growth of cancer cells (See page18), does not reasonably provide enablement for a composition and/or a method administering said composition to protect liver (Claims 32, 38, 43), cure cancer (Claims 33, 39 and 44) or prevent a myriad of diseases that are claimed in Claim 47 (e.g., cold, reduce stress alleviating pain) via instantly claimed composition or method of administering the instantly claimed food/pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification, while being enabling for a method to obtain claimed composition from Zang Zhi fruiting bodies and administer said composition to individuals in need of as a food/pharmaceutical composition, since does not particularly illustrate an example of a method to administer a composition to protect liver, cure cancer or prevent the diseases listed in Claim 47, the specification does not reasonably provide enablement to a method to protect liver, cure cancer or prevent the diseases listed in Claim 47 via the claimed method of administering the claimed pharmaceutical/food composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure applicants have merely mentioned administering a food/pharmaceutical composition comprising a dry powder obtained from Zang Zhi fruiting bodies to protect liver, cure cancer or prevent the diseases listed in Claim 47. While the specification discloses a comparative example, wherein growth of different types of cancer cells is inhibited with a composition comprising a composition obtained from Zang Zhi fruiting bodies (See Page18, Lines 1-22 of the specification of instant application), no clear data or example is given to demonstrate that said liver was protected, cancer was cured, or diseases listed in Claim 47 were protected with administration of said composition.

Inventions targeted for human therapy claiming method(s) of protecting/ cure or prevention of a certain ailment bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective cure/or prevention or prophylaxis of disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutical/ food compositions and to methods of administering compounds to human that would in effect " protect, cure or prevent" the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, applicants would have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient of the composition for the administration of the composition intended for a method of therapeutic treatment or prophylaxis. There is no

guidance in the specification, other than a method to demonstrate inhibition of a variety of cancer cells grown in media comprising a composition obtained from Zang Zhi fruiting bodies. Moreover, the instant application does not provide a working example providing data that shows that the method and composition of the instantly claimed invention would indeed prevent an event such as the claim designated disease conditions. Thus, applicants have not demonstrated the claimed functional effect of treating and/or preventing any and all cancers.

Accordingly, undue experimentation without a reasonable expectation of success as to how to determine which combination of each of the claims designated "food/pharmaceutical composition in which therapeutic amounts of any or all of the claimed designated components would be effective in the instantly claimed method to administer the instantly claimed composition to obtain the instantly claimed functional effect of protecting liver, cure cancer or prevent the diseases listed in Claim 47 would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

17. Claims 23 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a basidiomycete, "Zang Zhi" that produces a fruiting body composition applicable as food/pharmaceutical composition.

18. "Zang Zhi" is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism (s) is not so obtainable or available, a deposit of the microorganism (s) in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

Applicants have made a deposit at the Food Industry and Development Institute under the accession number CCRC 35398. However, in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807 which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository;
- and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit.

19. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

20. Claims 23 and 27-49 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 23 and 27-49 as written are very confusing, difficult to understand and thus indefinite. Applicants are requested to clearly, concisely and succinctly rewrite the claims in such a manner that the claims clearly indicate the applicants' invention. Applicants are reminded to ensure that no new matter is added while rewriting these claims clearly, concisely and succinctly.
- The recitations "characteristics" in Claims 23 and 27 and "characterized" in Claim 28 render those claims indefinite because the terms "characteristics" and "characterized" are ambiguous and, therefore, any limitations recited thereafter are unclear.
- Claims 23 and 27 recite the limitation "characteristics of physiological activities of triterpenoid as that of wild Zang Zhi". There is insufficient antecedent basis for this

limitation in the cited claim, because characteristics of said compound from fruiting bodies of said organism are not referred to before. Appropriate correction is required.

- Claims 23 and 27 are rendered vague and indefinite because of the phrase "Bag Log". The metes and bounds for the phrase "Bag Log" are not defined in claims and specification does not clarify this term, therefore, an artisan of ordinary skill would not understand the term. Applicants are requested to define or clarify the phrase "Bag Log".
- Claims 23 and 27 recite the limitation "saw dust medium". There is insufficient antecedent basis for this limitation in the cited claim, because the phrase "saw dust medium" is not defined in the claim. Appropriate correction is required.
- Term, "conoid" in claims 23 and 27 renders those claims unclear and therefore indefinite as the metes and bounds to distinguish this term from another have not been established. An artisan skilled in the art will not be able to distinguish among the terms as discussed above. Appropriate clarification is required.
- Claims 23 and 27 are rendered vague and indefinite because of the phrase "a period of time". What is meant by "a period of time", a day, an hour, a week, a month or several months? The metes and bounds for the phrase "a period of time" have not been established. Applicants are requested to define or clarify the phrase "a period of time".
- Claim 30 is rendered vague and indefinite because of the phrase "products of granule". The art-recognized phrase is "granular product". Appropriate correction is requested.
- Claim 37-41 are rendered vague and indefinite because these claims refer to a food composition comprised of only one ingredient (i.e., solid fruiting body of Zang Zhi). , but a composition is comprised of at least two components.
- Claims 37 and 42 recite the limitation "processed products thereof". There is insufficient antecedent basis for this limitation in those claims because Claim 27 from which claims 37 and 42 depend does not recite processed products of the fruiting body claimed in claim 27.
- Claim 41-46 are rendered vague and indefinite because these claims refer to a Pharmaceutical composition that does not recite an excipient.
- Claim 48 is rendered unclear and therefore, indefinite because the phrase "skin regeneration function and can be used as recovery material or body skin" does not clearly define the invention claimed. Appropriate clarification is requested.

All other claims (e.g., 38-41 and 42 to 46) depend directly from the rejected claims (e.g., 27, 37 and 42) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections – 35 U.S.C. § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims 23, 27-28, 31, 33-34 37, 39, 42, and 44 are rejected under 35 U.S.C. §102(b) as anticipated by Yang et al. (Phytochemistry, 41: 1389-1392, 1996), with evidence provided by Wu et al. (Bot. Bull, Acad. Sin. 38:273-275, 1997).

Claims recite a composition comprising fruiting bodies of Zang Zhi or a product obtained from said fruiting bodies, wherein said product is applicable to treat cancer.

Yang et al. disclose a composition comprising fruiting bodies of *Antrodia cinnamomea* or products obtained from said fruiting body (Title and Abstract). Said product is applicable as medicine to treat cancer among other ailments (Abstract, Lines 1-3). Please note that *Antrodia cinnamomea* is the synonym for *Antrodia camphorata* or *Ganoderma comphoratum* (See Wu et al, Page 274, Column 2, Lines 14-22) and applicants have accepted on record that *Antrodia camphorata* is synonym for Zang Zhi (See abstract, Line 2 of instant application). Yang et al. further teach isolating triterpenoids from *Antrodia cinnamomea* which is the compound claimed to have characteristic activity in fruiting bodies from Zang Zhi, i.e. the prior art composition, inherently must function as claimed because the microorganism disclosed in the prior art reference is the same microorganism and same component is obtained from said microorganism as is recited in the claimed invention.

Therefore, the reference anticipates the cited claim.

Please note that Wu et al. is cited merely to provide evidence to Yang et al. and not as a prior art.

Claim Rejections - 35 U.S.C. § 103

23. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

25. Claims 23 and 27-49 are rejected under 35 U.S.C. § 103 (a) as obvious over Yang et al. (Phytochemistry, 41: 1389-1392, 1996), with evidence provided by Wu et al. (Bot. Bull, Acad. Sin. 38:273-275, 1970) in view of Endrawanto (English Abstract, Proceeding of the Scientific Meeting on Research and Development of Isotope and Radiation Technology, 2000, Pages 169-173), Zhang et al. (Biosci. Biotech. Biochem. 58:1202-1205, 1994) and Wang (Rept. Taiwan Sugar Res. Inst.: 130, Pages 23-31, 1990).

Claims recite a composition obtained by cultivating a fungus, Zang Zhi, a method to prepare a composition from fruiting bodies of said fungus and application of said composition to ameliorate a number of ailments. The composition is comprised of fruiting body of said fungus and/or product comprising triterpenoids obtained from said fruiting body, wherein said fruiting body is obtained through the steps of cultivating spawns of said fungus in "Bag Logs" followed by subjecting said culture to grow in air. Said fruiting body or products obtained thereof (e.g., food or pharmaceutical compositions) protect liver, inhibit cancer cell growth and have anti-oxidant activity as well as skin regenerating activity.

Teachings from Yang et al. with evidence provided by Wu et al. have already been discussed *supra*. Please note that Yang et al. disclose that their composition also ameliorates skin itching

Yang et al., however, do not teach cultivation of fruiting bodies of Zang Zhi in "Bag Log" or amelioration of diseases (e.g., skin regeneration and antioxidant properties) other than cancer, nor do they teach that Zang Zhi is a mushroom.

Endrawanto teaches cultivating *Auricularia* mushroom in "Bag Log", wherein said "Bag Log" comprises sawdust, rice bran, calcium oxide, calcium sulfate, phosphorus fertilizer, urea, palm oil empty fruit bunch and sludge. Said "Bag Log" after sterilizing was inoculated with mushroom spawn and during the experiment mushroom (i.e., fruiting body) yield in different experimental treatments were evaluated (English Abstract, Lines 2-13). Endrawanto does not teach humidity and temperature conditions for incubating "Bag Log". Wang teaches that plastic bags containing a medium comprised of sawdust, wheat and rice were sterilized and subsequently inoculated with mycelia of mushrooms (e.g., *Auricularia* and *Ganoderma*). Subsequently, said bags were incubated at a temperature below 35° C and under relative humidity of 70-90% (Abstract on Page 24, Lines 9-15). Please note that relative humidity of 70-90% overlaps the relative humidity range of 60-80% and the culture media that Endrawanto and Wang teach was comprised of sawdust, wheat, rice, rice bran and inorganic salts. Thus, both Endrawanto and Wang teach cultivation of fruiting bodies of a fungus, wherein said fungus

is a mushroom and said "Bag Log" comprises cellulosic substances, saccharides, starchy substances (i.e., wheat and rice), millet (i.e., wheat bran) phosphates and sulfates. Furthermore, Zhang et al. teach that *Ganoderma* is a Chinese mushroom and composition from fruiting bodies of *Ganoderma* mushroom is antitumorogenic (Page 1205, Column 1, Lines 33-36). Please note that *Ganoderma comphoratum* is synonymous with *Antrodia camphorata* or *Antrodia cinnamomea* (See Wu et al., Page 274, Column 2, Lines 14-22). Thus, combined teachings from Endrawanto, Wang and Zhang et al. teach cultivation of fruiting body of a fungus in a "Bag Log", said "Bag Log" comprised of same nutrients as are recited in claimed invention, i.e. the prior art method, intrinsically teaches cultivation of fruiting body of same microorganism under same conditions of temperature, humidity, and substrate composition as is recited in the instantly claimed invention. Please note further that even though the compositions disclosed in the Examiner-cited prior art (i.e., Yang et al., Zhang et al.) do not refer to ameliorating all the diseases recited in the claimed invention, the claims remain obvious to an artisan of ordinary skill because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight.

One having ordinary skill in the art would have been motivated to modify the teachings from Yang et al. (Title and Abstract) according to teachings from Endrawanto (English Abstract, Lines 2-13), Wang (Abstract on Page 24, Lines 9-15) and Zhang et al. (Page 1205, Column 1, Lines 33-36), because said prior art references teach cultivating fruiting body of a fungus in a "Bag Log", wherein said "Bag Log" is comprised of a culture medium comprised of cellulosic substances, saccharides, starchy substances (i.e., wheat and rice), millet (i.e., wheat bran) phosphates and sulfates for cultivating fungal mycelium/fruiting body at a temperature below 35° C and relative humidity of 70-90% (Abstract on Page 24, Lines 9-15) and obtaining a composition comprising said fruiting body or products obtained therefrom, wherein said composition ameliorates a number of ailment (e.g., cancer, liver diseases, skin diseases, See, Yang et al., Title and Abstract) according to the teachings from Endrawanto (English Abstract, Lines 2-13), Wang (Abstract on Page 24, Lines 9-15) and Zhang et al. (Page 1205, Column 1, Lines 33-36). While Endrawanto and Wang remedy the deficiency in teachings of Yang et al., v of cultivating the fruiting body in a "Bag Log" under the conditions of cultivation recited in the instant invention, Zhang et al. further support Yang et al's teaching that the fruiting body is a mushroom and a product having antitumorogenic properties is obtained from said fruiting body.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Yang et al. with evidence provided by Wu et al. according to teachings from Endrawanto, Wang and Zhang et al. to obtain a composition comprising fruiting body of *Antrodia camphorata* through cultivating said fruiting body in "Bag Log" and to administer the composition comprising said fruiting body or a product obtained from said fruiting body to ameliorate cancer, skin disease, liver disease and diseases resulting from peroxide or free-radical reactions.

None of the above discussed prior art references teach the exact same concentrations/ materials/ components/ conditions to obtain exact yields of fruiting bodies of *Antrodia camphorata*. However, the adjustment of particular conventional working conditions (e.g., the quantities of each one of components in the medium contained in the "Bag Log", pH, temperature, length of incubation etc.) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

26. Applicants are also advised that claims 23 and 27-49 in the instant invention are product-by-process claims. As such, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. According to MPEP§2113, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). In instant invention, production of fungal/mushroom fruiting body and compositions/products obtained from said fruiting body to treat a myriad of ailments (e.g., cancer, stomachache, skin itching etc.) are well documented in the cited prior art.

Conclusion

27. No Claims are allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

April 17, 2003


CHRISTOPHER R. TATE
PRIMARY EXAMINER